K080291

MAR 19 2008

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**Applicant:**
Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, CA 94086
408.523.2100

**Manufacturing/ Distribution Address:**
Intuitive Surgical, Inc.
950 Kifer Road
Sunnyvale, CA 94086

**Establishment Registration Number:** 2955842

**Date submitted:** January 31, 2008

**Proprietary Name:** Intuitive Surgical *da Vinci* Surgical System, the *da Vinci* S Surgical System, and the EndoWrist Stabilizer

**Common Name:** Endoscopic Instruments, Control System and Accessories

**Classification Status:** Class II per 876.1500 - Endoscope and Accessories

**Product Codes:** NAY

**Predicate Devices:** Intuitive Surgical *da Vinci* Surgical System (K040237), the *da Vinci* S Surgical System (K050369), and the EndoWrist Stabilizer (K060391)

**Device Description:**

1. **The *da Vinci* Surgical System consists of three integrated sub-systems as follows:**

   **Endoscopic Instrument Control System:** The Endoscopic Instrument Control System is comprised of the Surgeon Console (Model IS1200-SSC), Patient Side Cart (Model IS1200-PSC) and a Stereo View Endoscopic Vision System (Model VS1000) that includes a stereo endoscope that provides a 3-dimensional view of the surgical field. While seated at the Surgeon Console, the surgeon controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field. Endoscopic instrument and camera movements are controlled by the surgeon, through the use of Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The endoscopic instruments are held in a fixed position (with respect to the patient) by either two (or optionally three) unique arms known as Patient Side Manipulators (PSM), which are located on the Patient Side Cart. The endoscope is also held in a fixed position (with respect to the patient) by another arm, similar to the PSM, known as the Endoscope Camera Manipulator (ECM) and also located on the PSC. Commands from the Surgeon

Console are relayed to the Patient Side Cart, which is located immediately adjacent to the patient, via cables. Instrument and endoscope changes are performed by another provider positioned adjacent to the Patient Side Cart.

**Stereo View Endoscopic Vision System**: The endoscopic vision system used with the da Vinci Surgical System, also known as Intuitive Surgical Insite® Vision System, Model VS1000, consists of a stereo endoscope, endoscopic camera, and various accessories, including a light source and light guides. The Insite Vision System provides two independent images that are relayed to the viewer located in the Surgeon Console, where, they are fused to form a 3-D (or alternatively a 2-D image) image of the surgical field.

**EndoWrist Instruments:** A full range of endoscopic surgical instruments is available to support the surgeon for a wide range of surgical tasks such as tissue manipulation, suturing, cutting, coagulation and clamping. Most instruments have a unique articulating design at their distal tips known as a "wrist" and these instruments provide seven degrees of motion (wrist pitch, wrist yaw, grip, roll, insertion, arm pitch, and arm yaw) that mimic the dexterity of the human hand and wrist. Quick-release levers facilitate instrument changes during surgical procedures, and the instruments have an electronic integrated circuit in their housing that identifies the instrument on the system. The instruments are programmed for a limited number of uses to ensure reliability and consistent performance, and the integrated circuit "expires" the instrument after a pre-determined number of uses have been reached.

**Note:** The da Vinci Surgical System (Model IS1200) cannot be used with the EndoWrist Stabilizer but can be used in conjunction with standard non-robotically operated stabilizers such as Octopus TE (Medtronic, Inc.).

2. **The *da Vinci S* Surgical System consists of three integrated sub-systems as follows:**

**Endoscopic Instrument Control System:** The Endoscopic Instrument Control System is comprised of the Surgeon Console (Model IS2000-SSC), Patient Side Cart (Model IS2000-PSC) and a Stereo View Endoscopic Vision System (Model VS2000) that includes a stereo endoscope that provides a 3-dimensional view of the surgical field. While seated at the Surgeon Console, the surgeon controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field. Endoscopic instrument and camera movements are controlled by the surgeon, through the use of Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The endoscopic instruments are held in a fixed position (with respect to the patient) by either two (or optionally three) unique arms known as Patient Side Manipulators (PSM), which are located on the Patient Side Cart. The endoscope is also held in a fixed position (with respect to the patient) by another arm, similar to the PSM, known as the Endoscope Camera Manipulator (ECM) and also located on the PSC. Commands from the Surgeon Console are relayed to the Patient Side Cart, which is located immediately adjacent to the patient, via cables. Instrument and endoscope changes are performed by another provider positioned adjacent to the Patient Side Cart.

**Stereo View Endoscopic Vision System**: The endoscopic vision system used with the da Vinci Surgical System, also known as Intuitive Surgical Insite® Vision System, Model VS1000, consists of a stereo endoscope, endoscopic camera, and various accessories, including a light source and light guides. The Insite Vision System provides two independent images that are relayed to the viewer located in the Surgeon Console, where, they are fused to form a 3-D (or alternatively a 2-D image) image of the surgical field.

**EndoWrist Instruments:** A full range of endoscopic surgical instruments is available to support the surgeon for a wide range of surgical tasks such as tissue manipulation, suturing, cutting, coagulation and clamping. Most instruments have a unique articulating design at their distal tips known as a "wrist" and these instruments provide seven degrees of motion (wrist pitch, wrist yaw, grip, roll, insertion, arm pitch, and arm yaw) that mimic the dexterity of the human hand and wrist. Quick-release levers facilitate instrument changes during surgical procedures, and the instruments have an electronic integrated circuit in their housing that identifies the instrument on the system. The instruments are programmed for a limited number of uses to ensure reliability and consistent performance, and the integrated circuit "expires" the instrument after a pre-determined number of uses have been reached.

## 3. The Intuitive Surgical EndoWrist Stabilizer

The Intuitive Surgical EndoWrist Stabilizer is used with the *da Vinci* Surgical System Model IS2000, which is also known as the *da Vinci® S™* Surgical System. The surgeon sits at a Surgeon Console and controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field through use of the Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The EndoWrist Stabilizer is operated in the same way as other Intuitive Surgical EndoWrist Instruments, and the surgeon "locks" the stabilizer in position by switching MTM control away from the arm holding the stabilizer instrument by tapping a foot pedal on the Surgeon Console.

The Intuitive Surgical EndoWrist Stabilizer is a multiple use instrument similar to existing EndoWrist instruments and has the following key features:

- The EndoWrist Stabilizer incorporates collapsible "pods" as grips that provide suction based tissue stabilization. The collapsible feature allows the instrument to be used through a 12mm thoracic port.
- A disposable, pre-packaged sterilized tubing assembly known as "ClearField" tubing is used to connect the instrument to pressurized irrigation fluid to irrigate the surgical site reducing the amount of blood on the stabilized tissue.
- A disposable, pre-packaged sterilized tubing assembly known as "CardioVac" tubing provides vacuum suction to the stabilizer pods from the Vacuum Source tubing described below.
- A disposable, pre-packaged sterilized tubing assembly known as "Vacuum Source" tubing that connects the CardioVac tubing to a canister with a four-meter vacuum hose, and also includes a two-meter vacuum hose (with filter) to connect to a regulated vacuum source.

**Note:** The Intuitive Surgical EndoWrist Stabilizer can only be used with the *da Vinci S* Surgical System and operated in the same way as other Intuitive Surgical EndoWrist Instruments. The surgeon manipulates and positions the stabilizer using the MTMs, and can "lock" the stabilizer in place by switching MTM control away from the arm holding the stabilizer instrument by tapping a foot pedal on the Surgeon Console.

**Indication for Use:**

**Device Name:** Intuitive Surgical *da Vinci* and *da Vinci S* Endoscopic Instrument Control System and Endoscopic Instruments

The *Intuitive Surgical*® Endoscopic Instrument Control System is intended to assist in the accurate control of *Intuitive Surgical*® Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing during general laparoscopic surgical procedures, general non-cardiovascular thoracoscopic surgical procedures and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

**Indications for Use:**

**Device Name:** Intuitive Surgical *Endowrist*® Stabilizer
For use with Intuitive Surgical Endoscopic Instrument Control System

The Intuitive Surgical EndoWrist Stabilizer Instrument is intended to be used with the 4rth arm da Vinci *S* Surgical System. The Intuitive Surgical EndoWrist Stabilizer Instrument is intended to stabilize the epicardial surface of the non-arrested heart during coronary artery surgery. It is intended to be used only by medical professionals in operating room environments.

**Substantial Equivalence Discussion:**

Intuitive Surgical has proposed a labeling modification for their *da Vinci* Surgical System (K040237), the *da Vinci* S Surgical System (K050369), and the EndoWrist Stabilizer (K060391) to remove the warning language regarding beating heart procedures. There is no change to the Indications for Use for any of the devices.
Based on the clinical experience of the da Vinci and da Vinci *S* Surgical Systems in beating heart surgical procedures to date, Intuitive Surgical has determined that there is now sufficient evidence to establish the performance of the da Vinci Surgical System, the da Vinci *S* Surgical System and the EndoWrist Stabilizer in beating heart procedures, and the removal of warning from the labeling for all three devices is clearly warranted. A detailed justification for this labeling modification was provided.

The modified *da Vinci* Surgical System (K040237), the *da Vinci* S Surgical System (K050369), and the EndoWrist Stabilizer (K060391) have the following similarities to those which previously received 510(k) clearance:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same device design,
- incorporates the same materials.

**Performance Data:** Since the subject devices are identical to the predicate devices and no design changes were implemented, performance testing was not required.

**Conclusion:**
The removal of the beating heart warning does not alter the fundamental scientific technology of the device because it does not change the devices' operating principles.

The *da Vinci* Surgical System, the *da Vinci* S Surgical System, and the EndoWrist Stabilizer described in this submission are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2008

Intuitive Surgical, Inc.
% Ms. Karen Uyesugi
VP, Clinical & Regulatory Affairs
950 Kifer Road
Sunnyvale, California 94086

Re: K080291
Trade/Device Name: Intuitive Surgical *Endowrist*® Stabilizer
For use with Intuitive Surgical Endoscopic Instrument Control System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NAY
Dated: January 31, 2008
Received: February 4, 2008

Dear Ms. Uyesugi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K080291

**Device Name:** Intuitive Surgical *Endowrist*® Stabilizer
For use with Intuitive Surgical Endoscopic Instrument Control System

**Indications for Use:**

The Intuitive Surgical EndoWrist Stabilizer Instrument is intended to be used with the 4rth arm *da Vinci S* Surgical System. The Intuitive Surgical EndoWrist Stabilizer Instrument is intended to stabilize the epicardial surface of the non-arrested heart during coronary artery surgery. It is intended to be used only by medical professionals in operating room environments.

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Janeta Z for

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K080291